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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,960	12/03/2003	James P. Beckham	FMED-26,553	4367

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HOWISON & ARNOTT, L.L.P  
P.O. BOX 741715  
DALLAS, TX 75374-1715

EXAMINER
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THOMPSON, MICHAEL M

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/726,960

Applicant(s)

BECKHAM, JAMES P.

Examiner

Michael M. Thompson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

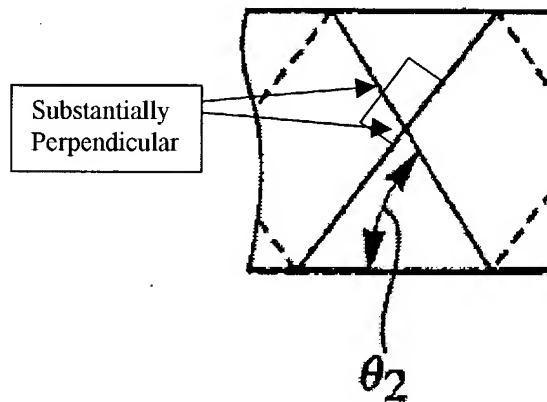
1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruiz (5,868,779) in view of Jorgensen. Ruiz teaches all of the limitations of the claims such as the teaching or PET as non-compliant material suitable for use except for multiple fiber/polymeric outer walls. Jorgensen teaches multiple fiber/polymeric outer walls that form an angle to one other for providing a lower compliance composite balloon device. It would have been obvious to one of ordinary skill in the art, at the time of invention to have modified the reinforced portion of Ruiz with the reinforced portion of Jorgensen to increase the number of outer fiber/polymeric walls as taught by Jorgensen and for the purpose of lowering compliance since it is well known that the more layers of non-compliant outer walls or mesh that are added serves to reduce compliance of the balloon structure. Furthermore, the Examiner maintains that the method of Jorgensen teaching a layering of outer walls/mesh is analogous to exchanging mesh of different compliance thereby providing additional motivation for their use in the medical art of balloon catheters and the selection of any of these known equivalents to create a reinforced medical device would be within the level of ordinary skill in the art at the time of invention. Furthermore, with respect to Applicant's fiber layer materials it is the Examiner's position that

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Jorgenson teaches polyethylene that meets Applicant's description of inelastic fibers. As shown below it is also the Examiner's position that the fiber layers are "substantially" at a right angle and they are "about" at an angle of 10 degrees.



In addressing the first fibers being equal in length to the long axis of the balloon, the Examiner submits that even though the fibers are helically wound, they are substantially the length of the long axis in that they do not appear to extend past the ends of the balloon section and run substantially the longitudinal length albeit in a helical fashion.

Furthermore, it is the Examiner's position that at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have provided fibers having a thickness of about 0.0005 inch and a second fiber layer wind density of 50 wraps per inch because Applicant has not disclosed that having fiber a thickness of about 0.0005 inch and a second fiber layer wind density of 50 wraps per inch provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a fiber thickness of 0.0010 or a second fiber layer wind density of 60 or 40 wraps per inch because

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both the fiber thickness and wind density perform the same function of providing similar non-compliant characteristics of preventing over inflation and elastic characteristic phenomenon and would have functioned equally well. Therefore, it would have been an obvious matter of design choice to modify Ruiz in view of Jorgensen to obtain the invention as specified.

### Contacts

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Michael Thompson whose telephone number is (703) 305-1619. The Examiner can normally be reached on Monday through Friday from 9 am to 5 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Primary, Brian Casler, can be reached on (703) 308-3552. The official fax phone number for all submissions to the organization where this application or proceeding is assigned is (703) 872-9306.

Michael M. Thompson

Patent Examiner



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May 01, 2004